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| APPLICATION NO. | . | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|-------------------------------------|----------------|----------------|-----------------------|-------------------------|-----------------|
| 10/802,555 | 555 03/30/2004 | | Vihar C. Surti | 10000/125 | 6408 |
| 757 | 7590 | 12/18/2006 | | EXAMINER | |
| | | GILSON & LIONE | KOHARSKI, CHRISTOPHER | | |
| P.O. BOX 10395 CHICAGO, IL 60610 | | | | ART UNIT | PAPER NUMBER |
| | | | | 3763 | |
| | | | | DATE MAILED: 12/18/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | 4.20 | | | | |
|--|--|--|--|--|--|--|
| , | Application No. | Applicant(s) | | | | |
| | 10/802,555 | SURTI, VIHAR C. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Christopher D. Koharski | 3763 | | | | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sheet with | the correspondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perions after the reply within the set or extended period for reply will, by state the provision of the provisions of 37 CFR after SIX (6) MONTHS from the mail the provisions of the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by state and provisions of the provisions of 37 CFR after SIX (6) MONTHS from the maximum statutory period for reply within the set or extended period for reply will, by state and provisions of the provision | DATE OF THIS COMMUNICA 1.136(a). In no event, however, may a reply of will apply and will expire SIX (6) MONTH tute, cause the application to become ABAN | TION. be timely filed from the mailing date of this communication. DONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 15 | November 2006. | | | | | |
| 2a) This action is FINAL . 2b) ⊠ Th | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| ,— | | | | | | |
| closed in accordance with the practice under | r <i>Ex parte Quayle</i> , 1935 C.D. 1 | 1, 453 O.G. 213. | | | | |
| Disposition of Claims | | · | | | | |
| 4) ☐ Claim(s) 1-18 is/are pending in the application 4a) Of the above claim(s) is/are withdrest is/are allowed. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-18 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and | rawn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9)☑ The specification is objected to by the Examination The drawing(s) filed on is/are: a)☐ and Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction. The oath or declaration is objected to by the | ccepted or b) objected to by ne drawing(s) be held in abeyance ection is required if the drawing(s) | . See 37 CFR 1.85(a). is objected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a li | ents have been received. ents have been received in Appriority documents have been re eau (PCT Rule 17.2(a)). | lication No ceived in this National Stage | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) | 4) Interview Sum | nmary (PTO-413) Aail Date | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date | | rmal Patent Application | | | | |

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DETAILED ACTION

Response to Amendment

Examiner acknowledges the filed RCE on 11/15/2006 that includes entered amended claims 1, 3, 5 and 18. Currently claims 1-18 are pending for examination in this application.

Response to Arguments

Applicant's arguments filed 11/15/2006 have been fully considered but they are not persuasive. Regarding claims 1-18 (under the Kane et al. reference, (6,985, 776), Applicant's representative asserts that the amended claim limitation containing magnets that are configured to abut an interior surface and are configured to approximate a force to the interior body overcome the prior art of record. Examiner disagrees with this assertion. Examiner asserts that the additional claim limitations are functional language with no associated structure; and therefore where the prior art reference is inherently capable of performing the function described in a functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, see In re Ludtke, 441 F.2d 660, 169 USPQ 563 (CCPA 1971). The Kane et al. reference is disclosed being used in the body and therefore is inherently capable of being used in other places in the body and the magnetic forces produced by the magnetic catheter tips are capable of creating an approximating force, Examiner suggests the following subject matter to overcome the prior art of record (see below).

Suggested Allowable Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner recommends either a method claim to support Applicant's intended invention or with claim 18 as a basis, adding additional claim limitations drawn to Applicant's specification [0027] including elements (26, 32) and the linking structure between catheters (38, 44).

Specification

The disclosure is objected to because of the following informalities: Upon further examination of the disclosure Examiner cannot find reference to drawing elements (26, 32). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6, and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Kane et al. (6,985,776). Kane et al. discloses a method and apparatus for cannulation.

Regarding claims 1, 3, and 5, Kane et al. discloses a device that has an elongate first and second member that contains a magnet (Figures 3, 6) that can either be energized or can be a permanent earth magnet (col 4-5) which would display a constant magnetic force that is capable of approximating a force to the interior of the body.

Additionally, the device is capable of being placed into a variety of body areas such as the upper and lower esophageal sac and abutting the interior surface thereof.

Regarding claims 2, 4, 6 and 10, Kane et al. discloses a device that has an upper and lower magnet that are configured to meet (Figure 7) with the elongate member containing a passageway with a flexible member connected to the magnet.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-8 are rejected under 35 U.S.C 103(a) as being unpatentable over Kane et al. in view of Rudie (3,771,526). Kane et al. meets the claim limitations as described above but does not include magnets shaped in the claim limitations.

However, Rudie teaches an anastomosis clamp. Regarding claims 7-8, the reference teaches the use of an anastomosis clamp system wherein the two engaging means are shaped in multiple ways to engage themselves (Figures 5 and 11).

At the time of the invention, it would have been obvious to use the shaped engaging means of Rudie with the magnet system of Kane et al. The addition of the surface modified tissue engaging regions provides a unique surface to meet and connect the tissues. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Rudie.

Claim Rejections - 35 USC § 103

Claims 9, 11-14, and 18 are rejected under 35 U.S.C 103(a) as being unpatentable over Kane et al. in view of Anderson (4,244,362). Kane et al. meets the

claim limitations as described above but does not include a balloon member and operative lumen.

However, Anderson teaches an endo-tracheal magnetic control device.

Regarding claims 9, 11-14, and 18, Anderson teaches a catheter device that that has a magnetic component that incorporates a balloon (17) assembly (Figures 1, 5) with an operative lumen and multiple flexible member lumens.

At the time of the invention, it would have been obvious to use the balloon assembly of Anderson with the system of Kane et al. because the addition of a balloon allows the catheter to be secured during the procedure. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Anderson.

Claim Rejections - 35 USC § 103

Claims 15-16 is rejected under 35 U.S.C 103(a) as being unpatentable over Kane et al. in view of Mager et al. (2003/0130610). Kane et al. meets the claim limitations as described above but does not include the gastric catheter with a plurality of ports.

Regarding claims 15-16, Mager et al. teaches catheter with a plurality of ports (106).

At the time of the invention, it would have been obvious to use the ports of Mager et al. with the catheter system of Kane et al. The addition of the multiple ports allows for the use of these ports for fluid removal or introduction of therapeutic drugs, or feeding

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liquids. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Mager et al.

Claim Rejections - 35 USC § 103

Claim 17 is rejected under 35 U.S.C 103(a) as being unpatentable over Kane et al. in view of Auzin et al. (2,308,484). Kane et al. meets the claim limitations as described above but does not include the distal element being secured by a band.

However, Auzin et al. teaches a general use inflatable catheter. Regarding claim 17, the reference teaches the use of band placed on the balloon to additional secure the balloon end and reinforces the assembly elements (Figure 6).

At the time of the invention, it would have been obvious to use the band assembly of Auzin et al. with the magnetic elements of Kane et al. The addition of the band attachment provides an easy method of construction and allows for the removal of the end distal elements. Both references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Auzin et al.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 12/06/2006

Christopher D. Koharski AU 3763